DETAILED ACTION

Response to Amendment

The amendment filed on 4/18/2008 has been received and claims 1-11 and 13-74 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/18/2008 has been entered.

Election/Restrictions

2. Claims 14-26 and 43-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/25/2007.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 27-30, 34-35, 39 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Ogle (20030229394).

As to Claims 27, 34-35 and 41, Ogle ('394) discloses a process for treating an implant so as to sterilize the implant prior to implantation (see entire document, particularly p.4 [0062]-[0063], specifically first five lines of [0063], where crosslinking is disclosed to eliminate antigens and to eliminate hyper-acute immune response and it is deemed that use of glutaraldehyde for crosslinking also will sterilize the tissue as glutaraldehyde is a known sterilant as well as a fixative/crosslinking agent), the implant comprising a soft tissue such as a tendon or ligament (see entire document, particularly p.6 [0077]-[0078] and p.10 [0108]), the process comprising:

applying tension to the soft tissue while contacting the soft tissue with a cleaning agent in the form of glutaraldehyde, which is a disinfecting agent and a decontaminating agent (see entire document, particularly p.10-11 paragraphs [0108]-[0113] and [0115]).

As to Claims 28-29, Ogle ('394) discloses that about 1 Newton of tension is applied to the soft tissue (see entire document, particularly p.10 [0109] and p.15 [0161] where 100 g weight provides about 1 Newton of tension).

As to Claim 30, Ogle ('394) discloses that about 3 Newtons to about 5 Newtons of tension are applied to the soft tissue (see entire document, particularly p.10 [0109]).

As to Claim 39, Ogle ('394) discloses that the process is further comprised of a step of contacting the implant with a rinsing fluid after contacting with the cleaning agent (see entire document, particularly p.11 [0118]).

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (20030229394) in view of Wolfinbarger (6024735).

Ogle ('394) is relied upon for disclosure described in the rejection of claim 27 under 35 U.S.C. 102(e).

As to Claim 38, Ogle ('394) does not appear to specifically teach that the process is further comprised of a step of contacting the implant with an alcohol before contact with the cleaning agent.

It was known in the art at the time of invention to provide a step of contacting an implant material with an alcohol before contacting with a cleaning agent. Wolfinbarger ('735) discloses a process of treating an implant so as to sterilize the implant prior to implantation (see entire document, particularly Abstract and Col. 1 lines 27-31) where the implant material is contacted with an alcohol (see entire document, particularly Col. 15 lines 31-35) before contacting with a cleaning agent (see entire document, particularly Col. 15 lines 54-58) in order to solubilize bone marrow and other contaminants associated with the implant material and thus to enhance the action of the cleaning solution (see entire document, particularly Col. 11 lines 24-26).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide a step of contacting an implant material with an alcohol prior to contacting with a cleaning agent in the process of Ogle in order to enhance the cleaning and sterilizing process for an implant material by solubilizing the bone marrow and other associated contaminants from the implant material prior to application of the cleaning agent so that the cleaning agent will be more effective as shown by Wolfinbarger.

As to Claim 42, Ogle ('394) does not appear to specifically teach that the implant comprises a tendon having bone attached thereto.

It was well known in the art at the time of invention to provide an implant material such as a tendon having bone attached thereto. Wolfinbarger ('735) exemplifies a process for treating an implant so as to sterilize the implant prior to implantation where the implant material is a tendon having bone attached (see entire document, particularly

Abstract and Col. 12 lines 50-51) in order to prepare an implant that is cleaned of blood deposits and other contaminants for use in clinical applications.

It would have been obvious to one of ordinary skill in this art at the time of invention to provide a tendon that is attached to a bone in the process of Ogle in order to clean/sterilize and to mechanically stabilize an implant material, that will experience a load in vivo, prior to implantation as exemplified by Wolfinbarger.

Thus, Claims 38 and 42 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Ogle ('394) and Wolfinbarger ('735).

7. Claims 1-5, 7-11, 13, 27, 31-42, 63-68 and 70-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (WO 00/29037) in view of Ogle (20030229394).

As to Claims 1, 27, 31-35, 38-39 and 63-64, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (see entire document, particularly Abstract), wherein the implant at least partially comprises a soft tissue (see entire document, particularly page 12, line 23), the process comprising:

(a) contacting the implant with a protective agent selected from the group consisting of alcohols and polyols (page 18, Table I Step 2 with fluid E; wherein during Step 2, alcohol is perfused into the implant – see p.18 line 20 to p.19 line 1);

(b) contacting the implant with an oxidizing sterilant (page 18, Table I Step 3 with fluid C which is hydrogen peroxide, that functions as a disinfectant and a

decontaminating agent, for about 1 minute, which is less than about 80 minutes; wherein during Step 3, peroxide is perfused into the implant – see p.19 lined 2-4); and

(c) contacting the implant with a rinsing fluid (page 18, Table I Step 4; page 19, lines 9-12 with fluid such as B, which is a detergent, and/or fluid E, which is an alcohol).

Mills ('037) does not appear to specifically teach that the method is further comprised of applying tension or kinematic restraint to the soft tissue at least during part of step (b) or at least during one of steps (a), (b) or (c).

It was known in the art at the time of invention to apply tension to an implant material such as a soft tissue while performing another step such as treating/contacting the implant with a fluid to eliminate antigens and/or terminate enzymatic activity. Ogle ('394) discloses a process for making an implant more suitable for implantation into a recipient (see entire document, particularly p.4 [0062]-[0063], specifically first five lines of [0063], where crosslinking is disclosed to eliminate antigens and to eliminate hyper-acute immune response and it is deemed that use of glutaraldehyde for crosslinking also will sterilize the tissue as glutaraldehyde is a known sterilant as well as a fixative/crosslinking agent), wherein the implant at least partially comprises a soft tissue (see entire document, particularly p.6 [0077]-[0078] and p.10 [0108]), the process comprising:

applying tension to the implant/soft tissue while the implant is being contacted with a sterilant (see entire document, particularly p.10-11 paragraphs [0108]-[0112], where glutaraldehyde is a known sterilant/ disinfecting agent/decontaminating agent as well as a fixative/crosslinking agent);

contacting the implant with a rinsing fluid after contacting with the sterilant (see entire document, particularly p.11 [0118]),

in order to reduce the processing time required to separately perform the two steps so as to produce an implant that is both mechanically stabilized and that had antigens and/or enzymatic activity to eradicate hyper-acute immune response, as well to produce an implant more structurally similar to a native tissue (see entire document, particularly p.4-5 [0063] and [0065], p.10 [0108]).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide the tensioning step at least during part of step (b) in the process of Mills in order to reduce the length of processing time required to perform the tensioning step and contact with a sterilant separate and to produce a mechanically stabilized and passivated implant as shown by Ogle.

As to Claim 13, while Ogle (‘394) discloses applying kinematic restraint to the soft tissue during at least part of step (b), to apply other types of fluid during the tensioning step when the implant is not contacted with a sterilant/crosslinker (see entire document, particularly p. 8 [0092]-[0094] and p.9 [0103]-[0104]), as well as disclosing that “other processing of the tissue can be performed simultaneously with the application of a load” (see first two lines of p.11 paragraph [0115]), Ogle ('394) does not appear to specifically teach that the fluid utilized during tensioning comprises a protective agent and a rinsing fluid.

However, it would have been obvious to one of ordinary skill in this art at the time of invention to tension the implant while carrying out the other steps (i.e. steps (a) as well as step (c)) in the process of Mills during tensioning step of Ogle in order to optimize the process by utilizing these fluid contacting/treating steps both to keep the implant moist during the tensioning step as well as to process/clean/sterilize/passivate the implant at the same time, so as to reduce the overall processing time (see entire Ogle ('394) document, particularly p.8 [0092]-[0094], p.9 [0103]-[0104], p.10 [0110] and first two lines of p.11 paragraph [0115]).

As to Claims 2 and 65, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein at least one of steps (a), (b) or (c) further comprises cyclically increasing and decreasing pressure during the contact with the implant (page 18, Table I Step 4 and page 19, lines 4-7 and 10-12).

As to Claims 3 and 66, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), further comprising:

d) contacting the implant with an oxidizing sterilant (page 19, lines 20-24; Table II); and

(e) contacting the implant with a rinsing fluid (page 20, Table II Step 4', or page 21, lines 1-3).

As to Claims 4, 40 and 67, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein at least one of steps (a) through (e) further comprises cyclically increasing and decreasing pressure during the contact with the implant (page 18, Table I Step 4 and page 19, lines 4-7 and 10-12, or page 20, Table II Step 4' and page 21, lines 1-3).

As to Claims 5 and 68, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), further comprising the step of rinsing the implant with an aqueous solution between steps (b) and (c) (page 18, Table I Step 4).

As to Claims 7 and 70, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the rinsing fluid is selected from the group consisting of alcohols, acetone, water, and mixtures thereof (page 18, Table I Step 4 with fluid E or mixtures; page 20, Table II Step 4' with fluid J or mixtures; page 19, lines 10-11; page 21, lines 1-2).

As to Claims 8 and 71, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the rinsing fluid comprises a monohydric alcohol having one to eight carbon atoms (page 18, Table I Step 4 with fluid E where the alcohol is "ethanol or isopropanol" or page 20, Table II Step 4' where the fluid is J – in the form of "isopropanol, methanol").

As to Claims 9 and 72, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein step (b) comprises contacting the implant with an aqueous solution comprising hydrogen peroxide in a concentration range of from about 1% to about 10% (page 18, Table I Step 3 with fluid C where the concentration is 3% or page 20, Table II with fluid I where the concentration is 6%).

As to Claims 10, 41 and 73, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the implant comprises at least one tendon or ligament (page 32, line 5).

Ogle ('394) also discloses that the implant comprising at least one tendon or ligament (see entire document, particularly p.6 [0077]-[0078] and p.10 [0108]).

As to Claims 11, 42 and 74, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the implant comprises a tendon having bone attached thereto (page 31, lines 21-31).

As to Claims 36-37, Mills ('037) discloses that the cleaning agent is selected from the group consisting of alcohols (see line 8 of p.18, fluid E), a detergent (fluid B –line 5 on p.18 - for Step 3 in Table I on p.18), and mixtures and combinations thereof (see line 9 of p.18).

Thus, Claims 1-5, 7-11, 13, 27, 31-42, 63-68 and 70-74 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of and .

8. Claims 6 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (WO 00/29037) in view of Ogle (20030229394) as applied to claims 1 and 13 above, and further in view of Wolfinbarger (6024735).

Mills ('037) and Ogle ('394) are relied upon for disclosure described in the rejection of claims 1 and 13 under 35 U.S.C. 103(a).

Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein prior to step (b) (for example during step (a)) alcohol is contacted with the implant (page 18, Table I Step 2 with fluid E).

Mills ('037) does not specifically teach that the implant contains an amount of the alcohol in the implant prior to step (b).

It was known in the art at the time of invention to contact an implant material comprising a soft tissue with alcohol where the alcohol remains within the implant prior to contact with an oxidizing sterilant. Wolfinbarger ('735) discloses a process of treating an implant so as to sterilize the implant prior to implantation (see entire document, particularly Abstract and Col. 1 lines 27-31) where the implant material is contacted with an alcohol (see entire document, particularly Col. 15 lines 31-35) before contacting with an oxidizing sterilant (see entire document, particularly Col. 15 lines 54-58), where the alcohol remains in the implant (see Col. 15 lines 65-66), in order to further solubilize and

reduce/remove bone marrow and other contaminants associated with the implant material (see entire document, particularly Col. 11 lines 24-26). It would have been obvious to one of ordinary skill in this art at the time of invention that the alcohol remains in the implant after the treatment in the process of Mills as shown by Wolfinbarger.

Thus, Claims 6 and 69 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Mills ('037), Ogle ('394) and Wolfinbarger ('735).

9. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (20030229394) in view of Wolfinbarger (6024735).

Ogle ('394) discloses a process for making an implant more suitable for implantation into a recipient (see entire document, particularly p.4 [0062]-[0063], specifically first five lines of [0063], where crosslinking is disclosed to eliminate antigens and to eliminate hyper-acute immune response and it is deemed that use of glutaraldehyde for crosslinking also will sterilize the tissue as glutaraldehyde is a known sterilant as well as a fixative/crosslinking agent), wherein the implant at least partially comprises a soft tissue (see entire document, particularly p.6 [0077]-[0078] and p.10 [0108]), the process comprising:

applying tension to the implant (see entire document, particularly p.10-11 paragraphs [0108]-[0112]); and

further processing the implant by perfusing the tensioned implant with a sterilizing solution such as an alcohol (see p. 10 [0118] which incorporates the US

patent application No. 09/480,437, now Pat. No. 6,471,723, wherein Col. 7 lines 4-5 and Col. 10 line 6 to Col. 11 line 1, where the use of an alcohol (i.e. ethanol) is disclosed).

While Ogle ('394) teaches that other processing of the tissue can be performed simultaneously with the application of a load (see first two lines of p.11 paragraph [0115]), Ogle ('394) does not appear to specifically teach that the process is also comprised of perfusing the tensioned implant with a peroxide for less than about 80 cumulative minutes.

It was well known in the art at the time of invention to perfuse an implant with a peroxide for less than about 80 cumulative minutes. Wolfinbarger ('735) exemplifies a process for making an implant more suitable for implantation into a recipient (see entire document, particularly Abstract and Col. 1 lines 27-31), wherein the implant at least partially comprises a soft tissue, the process comprising perfusing the implant with an alcohol (see Col. 15 lines 31-35) and perfusing the implant with a peroxide for less than about 80 cumulative minutes (see Col. 15 lines 54-58 and Col. 16 lines 42-49), in order to clean the implant of bone marrow and other contaminants without altering the properties of implant so as to reduce immunogenicity and viral load (see Col. 13 lines 1-5).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide a step of perfusing the implant with a peroxide for less than about 80 cumulative minutes in the process of Ogle in order to further process the implant so that the implant is suitable for implantation in a recipient (i.e. the implant will not cause an immunogenic response).

Thus, Claim 64 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Ogle ('394) and Wolfinbarger ('735).

Response to Declaration under 37 CFR 1.132

10. The declaration under 37 CFR 1.132 filed 4/18/2008 is insufficient to overcome the rejection of claims 1-11, 13, 27-2 and 63-74 based upon the references of Mills and Cook as set forth in the last Office action because: while the declaration provides data that appears indicate that implants tensioned while being sterilized are stronger than those that were not subjected to tension while being sterilized, it was well known that the step of tensioning implant materials yields implants that are stronger than un-tensioned implant material (see the reference of Ogle, particularly p.2 [0044]-[0045] and p.4 [0059]). In addition, the Applicant does not provide any data for samples that are tensioned separately from the sterilization process (pre-sterilization and/or post-sterilization) in order to show that simultaneous tensioning and sterilization of the implant material yields unexpected results beyond that expected from tensioning a sample separately from a sterilization step.

Therefore, as it was known to perform these steps (tensioning and sterilizing) separately where the tensioning step is known to yield implant material that is stronger than un-tensioned implant material (see the reference of Ogle, particularly p.2 [0044]-[0045] and p.4 [0059] and [0062]), without further showing of other unexpected results resulting from the combining these two known steps into one step, Examiner would take

the position that the improved strength shown in the declaration was predictable when known prior art elements are combined according to known methods.

Response to Arguments

11. Applicant's arguments with respect to claims 1-11, 13, 27-42 and 63-74 have been considered but are moot in view of the new ground(s) of rejection.

12. Applicant's arguments filed 4/18/2008 have been fully considered but they are not persuasive.

Specifically, in response to applicant's argument that “claimed process yields unexpected results…[from] applying tension to tendons during the sterilization process yield tendons having improved strength as compared to non-tensioned tendons” especially regarding “the collagen degradation results set forth in Table 1” in the Specification, Examiner would agree that the results of "the collagen degradation measured for the non-tensioned implants was higher than for the tensioned implant...even considering the standard deviation, the results do not overlap". However, Examiner would point to the explanation provided above in paragraph 10 of the current rejection and the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references relate either to the field of the invention or subject matter of the invention, but are not relied upon in the rejection of record: 20010018619, 20030014126.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REGINA YOO whose telephone number is (571)272-6690. The examiner can normally be reached on Monday-Friday, 10:00 am - 7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

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